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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/637,530	08/11/2000	Clifford P. Stanners	186.009US1	7274

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EXAMINER	
RAWLINGS, STEPHEN L	

ART UNIT	PAPER NUMBER
1642	20

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/637,530	Applicant(s) STANNERS ET AL.	
	Examiner Stephen L. Rawlings, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2003* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *12-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Election facsimile cover sheet* .

DETAILED ACTION

1. The amendment filed August 11, 2000 in Paper No. 5 is acknowledged and has been entered. Claims 1-11 have been canceled. Claims 12-25 have been added.

2. The amendment filed October 31, 2002 in Paper No. 14 is acknowledged and has been entered.

3. The amendment filed August 11, 2003 in Paper No. 18 is acknowledged and has been entered. Claims 12, 14, 15, 20, 21, 24, and 25 have been amended.

4. Claims 12-25 are pending in the application and are currently subject to the following restriction.

Election/Restrictions

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 12 and 13, insofar as the claims are drawn to an anti-CEA/NCA antibody that interacts with the subdomain of CEA/NCA that is SEQ ID NO: 1, classified in class 530, subclass 387.9.

Group II. Claims 12 and 13, insofar as the claims are drawn to an anti-CEA/NCA antibody that interacts with the subdomain of CEA/NCA that is SEQ ID NO: 2, classified in class 530, subclass 387.9.

Group III. Claims 12 and 13, insofar as the claims are drawn to an anti-CEA/NCA antibody that interacts with the subdomain of CEA/NCA that is SEQ ID NO: 25, classified in class 530, subclass 387.9.

Group IV. Claims 14, 15, and 21, insofar as the claims are drawn to a method for selecting a peptide or peptide-derived mimetic that can modulate a differentiation-blocking activity associated with the subdomain of CEA/NCA that is SEQ ID NO: 1, which cannot be classified because claim 14 recites no active process steps, and a peptide and/or peptide-derived mimetic obtained by said method, classified, for example, in class 530, subclass 300.

Group V. Claims 14, 15, and 21, insofar as the claims are drawn to a method for selecting a peptide or peptide-derived mimetic that can modulate a differentiation-blocking activity associated with the subdomain of CEA/NCA that is SEQ ID NO: 2, which cannot be classified because claim 14 recites no active process steps, and a peptide and/or peptide-derived mimetic obtained by said method, classified, for example, in class 530, subclass 300.

Group VI. Claims 14, 15, and 21, insofar as the claims are drawn to a method for selecting a peptide or peptide-derived mimetic that can modulate a differentiation-blocking activity associated with the subdomain of CEA/NCA that is SEQ ID NO: 25, which cannot be classified because claim 14 recites no active process steps, and a peptide and/or peptide-derived mimetic obtained by said method, classified, for example, in class 530, subclass 300.

Group VII. Claim 14, insofar as the claim is drawn to a method for selecting a peptide or peptide-derived mimetic that can modulate a differentiation-blocking activity associated with a subdomain of CEA/NCA that is a sequence including epitopes of 3 to 6 amino acids of the N-terminal 107 amino acids, which cannot be classified because claim 14 recites no active process steps.

Group VIII. Claim 14, insofar as the claim is drawn to a method for selecting a peptide or peptide-derived mimetic that can modulate a differentiation-blocking activity associated with a subdomain of CEA/NCA that is a sequence including epitopes of 3 to 6 amino acids of the internal A3B3 178 amino acids, which cannot be classified because claim 14 recites no active process steps.

Group IX. Claim 16, drawn to a shankless anchor, classified in class 530, subclass 300.

Group X. Claims 17 and 18, insofar as the claims are drawn to a method to restore endogenous integrin function, wherein said method comprises administering an antibody, classified in class 424, subclass 130.1.

Group XI. Claims 17 and 18, insofar as the claims are drawn to a method to restore endogenous integrin function, wherein said method comprises administering a peptide or peptide-derived mimetic, classified in class 514, subclass 2.

Group XII. Claims 19, 22, and 23, drawn to a drug screen assay, classified in class 435, subclass 377.

Group XIII. Claims 20 and 24, insofar as the claims are drawn to a method for enhancing the efficacy of a cytotoxic drug comprising incubating tumor cells with an agent that interferes with the subdomain of CEA/NCA that is SEQ ID NO: 1, wherein said agent is an anti-CEA/NCA antibody that interacts with the subdomain of CEA/NCA that is SEQ ID NO: 1, classified in class 424, subclass 139.1.

Group XIV. Claims 20 and 24, insofar as the claims are drawn to a method for enhancing the efficacy of a cytotoxic drug comprising incubating tumor cells with an agent that interferes with the subdomain of CEA/NCA that is SEQ ID NO: 1, wherein said agent is an anti-CEA/NCA antibody that interacts with the subdomain of CEA/NCA that is SEQ ID NO: 2, classified in class 424, subclass 139.1.

Group XV. Claims 20 and 24, insofar as the claims are drawn to a method for enhancing the efficacy of a cytotoxic drug comprising incubating tumor cells with an agent that interferes with the subdomain of CEA/NCA that is SEQ ID NO: 1, wherein said agent is an anti-CEA/NCA antibody that interacts with the subdomain of CEA/NCA that is SEQ ID NO: 25, classified in class 424, subclass 139.1.

Group XVI. Claims 20 and 24, insofar as the claims are drawn to a method for enhancing the efficacy of a cytotoxic drug comprising incubating tumor cells with an agent that interferes with the subdomain of CEA/NCA that is SEQ ID NO: 1, wherein said agent is a peptide having the sequence of SEQ ID NO: 1, or a mimetic thereof, classified in class 514, subclass 2.

Group XVII. Claims 20 and 24, insofar as the claims are drawn to a method for enhancing the efficacy of a cytotoxic drug comprising incubating tumor cells with an agent that interferes with the subdomain of CEA/NCA that is SEQ ID NO: 1, wherein said agent is a peptide having the sequence of SEQ ID NO: 2, or a mimetic thereof, classified in class 514, subclass 2.

Group XVIII. Claims 20 and 24, insofar as the claims are drawn to a method for enhancing the efficacy of a cytotoxic drug comprising incubating tumor cells with an agent that interferes with the subdomain of CEA/NCA that is

SEQ ID NO: 1, wherein said agent is a peptide having the sequence of SEQ ID NO: 25, or a mimetic thereof, classified in class 514, subclass 2.

Group XIX. Claim 20, insofar as the claim is drawn to a method for enhancing the efficacy of a cytotoxic drug comprising incubating tumor cells with an agent that interferes with $\alpha_5\beta_1$ integrin, which cannot be classified because the chemical and biologic nature of the agent is unspecified.

Note: Claim 24 has not been included in group XIX, because it cannot be determined which, if any of the specific agents recited in claim 24 is capable of interfering with $\alpha_5\beta_1$ integrin.

Group XX. Claim 20, insofar as the claim is drawn to a method for enhancing the efficacy of a cytotoxic drug comprising incubating tumor cells with an agent that interferes with $\alpha_v\beta_3$ integrin, which cannot be classified because the chemical and biologic nature of the agent is unspecified.

Note: Claim 24 has not been included in group XX, because it cannot be determined which, if any of the specific agents recited in claim 24 is capable of interfering with $\alpha_v\beta_3$ integrin.

Group XXI. Claim 20 and 24, insofar as the claims are drawn to a method for enhancing the efficacy of a cytotoxic drug comprising incubating tumor cells with an agent, wherein said agent is an antisense of CEA/NEA, classified in class 514, subclass 44.

Group XXII. Claim 20 and 24, insofar as the claims are drawn to a method for enhancing the efficacy of a cytotoxic drug comprising incubating tumor cells with an agent, wherein said agent is a shankless anchor of CEA/NCA

comprising a GPI anchor of CEA without the external domains thereof, classified in class 514, subclass 12.

Group XXIII. Claim 25, insofar as the claim is drawn to a method for relieving a CEA/NCA-imposed inhibition of differentiation and/or apoptosis comprising incubating tumor cells with an agent that disrupts an interaction of a CEA/NCA subdomain having SEQ ID NO: 1, classified in class 435, subclass 377.

Group XXIV. Claim 25, insofar as the claim is drawn to a method for relieving a CEA/NCA-imposed inhibition of differentiation and/or apoptosis comprising incubating tumor cells with an agent that disrupts an interaction of a CEA/NCA subdomain having SEQ ID NO: 2, classified in class 435, subclass 377.

Group XXV. Claim 25, insofar as the claim is drawn to a method for relieving a CEA/NCA-imposed inhibition of differentiation and/or apoptosis comprising incubating tumor cells with an agent that disrupts an interaction of a CEA/NCA subdomain having SEQ ID NO: 25, classified in class 435, subclass 377.

6. The inventions are distinct, each from the other because of the following reasons:

The inventions in groups I-III and IX are disclosed as biologically and chemically distinct, unrelated in structure and/or function, and/or made by and/or used in different methods, and therefore the claimed products are distinct.

The inventions in groups IV-VIII and X-XXXV are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success, and therefore the claimed methods are distinct.

Inventions in group IX and group XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the shankless anchor can be used in a materially different process of using that product, such as in the process of producing an antibody that binds specifically to the shankless anchor, which uses the shankless anchor as an immunogen.

The inventions in groups I-III and groups IV-VIII and X-XXXV are not at all related because the products of groups I-III are not specifically used in any of the steps of the claimed methods in groups IV-VIII and X-XXXV.

7. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Claim 20 is a linking claim. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, namely claim 20. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claim are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the

provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

9. Claim 19 is generic to a plurality of disclosed patentably distinct species comprising the method of claim 19 wherein said cell is selected from the group consisting of (a) a rat L6 myoblast according to claim 22 and (b) a human Caco-2 colonocyte according to claim 23. Applicants are required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should Applicants traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

S Rawlings
STEPHEN RAWLINGS

slr
September 30, 2003

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